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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/675,705	09/30/2003	Mark S. Ortiz	END5102.0515147	6304

7590 01/24/2007  
FROST BROWN TODD LLC  
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EXAMINER
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POUS, NATALIE R

ART UNIT	PAPER NUMBER
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3731

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	01/24/2007	PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/675,705	<b>Applicant(s)</b> ORTIZ, MARK S.	
	<b>Examiner</b> Natalie Pous	<b>Art Unit</b> 3731	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 13 November 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-5, 8-12 and 33 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-5, 8-12 and 33 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)            | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>10/18/04, 11/07/06</u> .                                      | 6) <input type="checkbox"/> Other: _____                          |

## **DETAILED ACTION**

### ***Response to Arguments***

Applicant's arguments with respect to claims 1-5, 8-12 and 33 have been considered but are moot in view of the new ground(s) of rejection. Examiner thanks applicant for explanation regarding the difference between the terms "biodegradable" and "biofragmentable." For the purpose of examination, examiner will read the term "biofragmentable" as capable of breaking into portions small enough to be eliminated through the body.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-3, 9-11 and 33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Huebsch (5853422) in view of Solymar et al. (US 6949116)

Huebsch teaches a device capable of forming an anastomosis between two gastrointestinal tissue lumens of a gastrointestinal tract comprising:

- a proximal ring (16); a distal ring (14);
- a plurality of proximal arms (22) each attached to the proximal ring at one end and having a distally directed other end;
- a plurality of distal arms (22) attached to the distal ring at one end and having a proximally directed other end; a center portion (18) coupling the proximal end of each distal arm to the distal end of each proximal arm;
- a latching mechanism (128) operably configured to lock at a reduced longitudinal spacing two selected from a group consisting of the proximal ring, the distal ring, and the center portion;
- wherein device forms a cylindrical shape when unactuated (fig. 2) and wherein the proximal and distal arms each outwardly extend when actuated to form a rivet shape (fig. 4).
- wherein the center portion comprises a center ring (18) aligned and interposed between the proximal (16) and distal (14) rings.
- wherein the proximal arms are radially aligned with the distal arms (fig. 3)
- wherein the latching mechanism comprises at least one interiorly disposed hook (128).
- wherein the latching mechanism comprises an interference fit (122, 124) formed between rings.
- wherein the proximal and distal arms (22) each include a hinge (24)

Huebsch fails to teach wherein at least a portion of the anastomosis device consists of a polymer biofragmentable material sufficient for facilitating fragmentation of the entire anastomosis device into fragments small enough for disengagement with the two lumens and elimination through the gastrointestinal tract. Solymar teaches a device for forming a connection between two body portions wherein the device consists of a biofragmentable polymer (Column 5, proximate lines 33-55 and claim 16) in order to provide a device that serves the purpose of holding two portions of tissue in apposition for a time and then allowing the tissue to stay in apposition on its own without the device exhibiting dimensional distortion or other effects while degrading. It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the device of Huebsch as taught by Solymar in order to provide a device that serves the purpose of holding two portions of tissue in apposition for a time and then allowing the tissue to stay in apposition on its own without the device exhibiting dimensional distortion or other effects while degrading.

Claim 8 is rejected under 35 U.S.C. 103(a) as obvious over Huebsch et al (US 5853422) in view of Solymar.

Claim 8 is being treated as a product by process limitation, in that the "sheet material, cylindrically formed onto a mandrel, and opposing longitudinal edges attaches one to another," refers to the process of making the device and not to the final product created. As set forth in the MPEP 2113, "Even though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself.

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The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior art was made by a different process." In re Thorpe, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985) (citations omitted) (See MPEP §2113). Examiner will thus evaluate the product claims without giving much weight to the method of its manufacture.

Thus, in this case, a device made from a rectangular sheet of material with fused edges is directed to the method of making the device and not the final product made. It appears the product disclosed by Huebsch would be the same and would perform equally well as that *claimed*; especially since both applicant's product and the prior art have the same final shape and structure of a device having proximal, distal and central rings, with longitudinally extending arms connecting the rings.

Claim 5, is rejected under 35 U.S.C. 103(a) as being unpatentable over the combination of Huebsch Solymar in view of Berg (US 6712836).

Regarding the limitations wherein device comprises a radiopaque material, the combination of Huebsch and Solymar teaches all limitations of preceding dependent claims 1 and 13 as previously described, but fails to disclose wherein the device comprises a radiopaque target material. Berg teaches a device comprising a radiopaque material in order to view the device during deployment using imaging techniques to determine the device is deployed at the proper location. It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the combination of Huebsch and Solymar with a radiopaque material as taught

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by Berg in order to view the device during deployment using imaging techniques to determine the device is deployed at the proper location

Claim 12 is rejected under 35 U.S.C. 103(a) as being unpatentable over the combination of Huebsch and Solymar in view of Barra et al. (US 5843088). The combination of Huebsch and Solymar teaches all limitations of preceding dependent claims 1 and 11 as previously described, but fails to disclose wherein a pad is outwardly disposed on each inner arm segment. Barra teaches a device wherein pads (6) are disposed on the portion touching tissue in order to gently rest the device on the tissue. It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the combination of Huebsch and Solymar with pads on the portion of the device touching tissue in order to allow the device to gently rest on the tissue.

Claim 4, is rejected under 35 U.S.C. 103(a) as being unpatentable over the combination of Huebsch and Solymar in view of Corcoran (US 6379368). The combination of Huebsch and Solymar teaches all limitations of preceding dependent claim 1, and further teaches the following:

- a proximal ring (Huebsch 16)
- a distal ring (Huebsch 14); a plurality of proximal arms (Huebsch 22) each attached to the proximal ring at one end and having a distally directed other end
- a plurality of distal arms (Huebsch 22) attached to the distal ring at one end and having a proximally directed other end
- a center ring (Huebsch 18) coupling the proximal end of each distal arm to the distal end of each proximal arm

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- a latching mechanism (Huebsch 128) operably configured to lock at a reduced longitudinal spacing two selected from a group consisting of the proximal ring, the distal ring, and the center ring
- wherein the anastomosis device forms a cylindrical shape when unactuated (Huebsch fig. 2) and wherein the proximal and distal arms each outwardly extend when actuated to form a rivet shape (Huebsch fig. 4).

The combination of Huebsch and Solymar fails to teach wherein the proximal arms are radially staggered with the distal arms. Corcoran teaches a device wherein the proximal extending tissue contacting portions are staggered with respect to the distal extending tissue contacting portions as seen in fig. 1 in order to allow the device to be used in a variety of physical anomalies of a variety of sizes and shapes. It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the combination of Huebsch and Solymar with staggered tissue contacting portions on the proximal and distal sides in order to allow the device to be used in a variety of physical anomalies of a variety of sizes and shapes.

### ***Conclusion***

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within



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TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Natalie Pous whose telephone number is (571) 272-6140. The examiner can normally be reached on Monday-Friday 8:00am-5:30pm, off every 2nd Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anhtuan Nguyen can be reached on (571) 272-4963. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

NRP  
1/17/07

  
**ANH TUAN T. NGUYEN**  
**SUPERVISORY PATENT EXAMINER**  
